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EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,175

Applicant(s)

Paufique

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jan 22, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-4 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-4 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. 09/482,885.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2

6) Other: _____

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DETAILED ACTION

Priority

Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in parent Application No. 09/482,885 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be made in this application. In making such claim, applicant may simply identify the application containing the priority papers.

This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a divisional of Application No. 09/482,885 now abandoned, filed on January 14, 2000." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "so as to" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Claim 1 recites the limitation "the different molecular species" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Regarding claims 3 and 4, the phrase "such that" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hasegawa et al. (N, Translation of the foreign patent document provided herein).

Applicant claims a process for firming the skin to counter the effects of aging, comprising applying to the skin of a person in need of the same a cosmetologically effective amount of a composition obtained from wheat proteins by crushing grains of fresh wheat so as to obtain a flour, dissolving this flour in water, hydrolyzing the solution thus obtained in the presence of proteases, separating the soluble and insoluble phases in the hydrolyzed material, and concentrating the active principle thus obtained, the molar mass of the different molecular

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species present having a principal peak at about 15,000 Daltons. Applicant further claims a process as claimed in claim 1, wherein said flour is solubilized in an amount of at least 80 g/l of water. Applicant further claims a process as claimed in claim 1, wherein the conditions of said hydrolysis are such that the pH is maintained constant between 4.0 and 10.0. Applicant further claims a process as claimed in claim 1, wherein the conditions of said hydrolysis are such that the temperature is maintained between 30 and 80°C.

Hasegawa teaches a process for firming the skin comprising applying to the skin of a person in need thereof a cosmetologically effective amount of a composition obtained from wheat proteins having a molecular weight at about 1,000 - 20,000 Daltons. In an example, Hasegawa teaches that a commercially available wheat flour (200g) was washed with water and kept at pH of 8 with sodium hydrogen carbonate. A protease (e.g., trypsin, pepsin or peptidase) was added to the above mixture at 37°C to carry out hydrolysis. See page 7 of the translated document at [0010]. Then, the mixture was heated at 70°C to deactivate the enzyme. After cooling to 40°C and adjusting at pH 7 with diluted hydrochloric acid, amylase was added to carry out hydrolysis of starch. The mixture was heated at 80°C to deactivate the enzyme, and filtered. The obtained solution was concentrated at 60°C until the solution reached to half a volume. The concentration was purified, adjusted at pH 4.5, and further filtered to obtain the material for use as an external skin medicament. In the translated document, on page 7 at [0011], Hasegawa teaches that the disclosed hydrolyzed protein has an average molecular weight between 1,000 and 20,000 and is water-soluble. On page 13 at [0018], Hasegawa teaches that the disclosed

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composition keeps moisture in human skin even in a low humidity environment. In the translated document, on page 6 at [0007], Hasegawa teaches that “the term ‘moisture retention’ does not only include retaining moisture, but also include softening, film-forming, smoothness, or the like together.”

Hasegawa discloses a method of using and making a composition obtained from wheat proteins that appears to be identical to the presently claimed method of using the disclosed composition and method of making thereof. Consequently, the claimed process appears to be anticipated by the aforementioned reference. The burden is on the applicant to prove that the claimed process is indeed novel and not anticipated by the prior art reference. The application, as presented, fails to do so.

However, even if the referenced process for firming the skin comprising the application of the referenced product-by-process and the claimed process for firming the skin comprising the application of the claimed product-by-process are not one and the same and there is, in fact, no anticipation, the referenced process would, nevertheless, have rendered the claimed process obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clear close relationship between the process steps of using and making the claimed product-by-process as evidenced by their belonging to the same plant species, method of making, method of using and their very similar disclosed properties. For instance, it would appear that the disclosed process and the claimed process have only slight differences in that the instantly claimed process discloses the use of fresh wheat flour, that the flour is solubilized in an amount

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of at least about 80 g/l of water, and that the obtained active principle has a molar mass peak at about 15,000 Daltons. It is not clear from the teachings of Hasegawa whether the commercially available wheat flour used in the making of the referenced composition was made from fresh wheat flour or whether the referenced product has the claimed "molar mass of the different molecular species present having a principal peak at about 15,000", but, it is noted that Hasegawa does teach adding 200 g of the wheat flour to an undisclosed amount of water; however, there is nothing in the reference to suggest anything contrary to the disclosed invention. Moreover, Hasegawa expressly teaches on page 4 under [0002], "Especially, the one having a molecular weight approximately between 1,000 and 20,000 is preferable because of its water solubility and its effect when is compounded in the skincare products for external use." At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to modify the method of making the wheat protein product which is used in the making of a skin care product taught by Hasegawa because Hasegawa teaches the requisite ingredients, the experimental conditions, and the physical properties of the final product which provides the beneficial functional effect for firming the skin. Thus, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the amounts of the ingredients and the source of the ingredients used in the making of the claimed composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to select result-effect amounts and degrees of freshness of the claimed ingredients to provide a

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composition with the claimed functional effect and claimed physical properties. Thus, it would appear that the claimed invention is no more than the routine optimization of result effect variables.

The United States Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether on not Applicants' skin care wheat product differs and, if so, to what extent, from that discussed in the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to Applicants.

Thus, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.


MCF

December 6, 2002